

Message Text

UNCLASSIFIED

PAGE 01 STATE 204698
ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-07 /026 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CM
APPROVED BY OES/APT/BMP:MCRAWFORD
DHEW/OIH: RFISCHER
EUR/CE:SKLINGAMAN(INFO)
EUR/NE:DDONCHI(INFO)
EUR/NE:REWOODS(INFO)
EUR/CWSCHALLER(INFO)

-----084036 270729Z /21

R 262038Z AUG 77
FM SECSTATE WASHDC
TO AMEMBASSY COPENHAGEN
AMEMBASSY OSLO
AMEMBASSY STOCKHOLM
AMEMBASSY BONN

UNCLAS STATE 204698

E.O. 11652: N/A

TAGS: OGEN, OTRA, ETRD, EIND, TBIO, DA, NO, SW, GW

SUBJECT: FDA REPRESENTATIVE PROVIDING TECHNICAL AND
CONSULTATIVE ASSISTANCE TO FOREIGN DEVICE MANUFACTURERS

1. FDA ADVISES THAT MR. JAMES BUMILLER OF THE OFFICE OF THE
EXECUTIVE DIRECTOR OF REGIONAL OPERATIONS WILL BE IN EUROPE
OCTOBER 15-NOVEMBER 3, 1977.

2. MR. BUMILLER WILL VISIT FIVE DEVICE MANUFACTURING FIRMS
TO DETERMINE IF THEIR FACILITIES AND OPERATIONS ARE IN
ACCORDANCE WITH CURRENT GOOD MANUFACTURING PRACTICE
REGULATIONS AND WILL REPORT ANY SIGNIFICANT DEVIATIONS WHICH
WOULD HAVE AN ADVERSE EFFECT UPON THE SAFETY AND/OR EFFICACY
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OF SUCH DEVICES THEY MAY IMPORT INTO THE UNITED STATES.

3. ITINERARY AS FOLLOWS:

OCTOBER 14, 1977 DEPART WASHINGTON, D.C. FOR COPENHAGEN,
DENMARK
OCTOBER 17-19 VISIT DAKO

OCTOBER 19 TRAVEL COPENHAGEN TO OSLO

OCTOBER 20,21,24 VISIT NYEGAARD (OSLO)

OCTOBER 25,26 VISIT NYEGAARD (LINDESNES)

OCTOBER 26 TRAVEL OSLO TO MALMO

OCTOBER 27-29 VISIT FERROSAN

OCTOBER 29 TRAVEL MALMO TO HEIDELBERG

OCTOBER 31, AND

NOVEMBER 1-2 VISIT SERVA

NOVEMBER 3 DEPART HEIDELBERG FOR WASHINGTON, D.C.

4. ASSISTANCE OF EMBASSIES WILL NOT BE REQUIRED. CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: TECHNICAL ASSISTANCE, ITINERARY, FOREIGN ASSISTANCE, VISITS
Control Number: n/a
Copy: SINGLE
Sent Date: 26-Aug-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE204698
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CM
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770310-0663
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770817/aaaaaoda.tel
Line Count: 74
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: f5f3df51-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 07-Dec-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1465270
Secure: OPEN
Status: NATIVE
Subject: FDA REPRESENTATIVE PROVIDING TECHNICAL AND CONSULTATIVE ASSISTANCE TO FOREIGN DEVICE MANUFACTURERS
TAGS: OGEN, OTRA, ETRD, EIND, TBIO, DA, NO, SW, GE, US, (BUMILLER, JAMES)
To: COPENHAGEN OSLO MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/f5f3df51-c288-dd11-92da-001cc4696bcc
Review Markings:
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